

# A breast-feeding promotion and support program a randomized trial in The Netherlands

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## A breast-feeding promotion and support program a randomized trial in the Netherlands

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### Abstract

**Background.** In the Netherlands, the initiation rate of breast-feeding (BF) was 80% in 2002, but only 35% of the mothers continued to breast-feed for 3 months. This study examined the effectiveness of a breast-feeding promotion program to increase the continuation of breast-feeding.

**Methods.** A cluster-randomized intervention trial was used. Ten child health care centers in three regions of the home health care were randomly allocated to the program or usual care. Elements in the program were health counseling, measures to enhance cooperation, early signaling of breast-feeding problems and continuity of care, and lactation consultancy. Pregnant mothers who applied for home health care in the intervention or usual care regions were enrolled and were followed up from pregnancy until 6 months postpartum ( $n = 683$ ). The primary outcome measure was the continuation of breast-feeding until at least 3 months.

**Results.** The 3-month breast-feeding rate was 32% in the intervention and 38% in the control groups (OR = 0.79, 95% CI = 0.58–1.08).

**Conclusion.** The program was not effective. We discuss possible explanations from the design and execution of the trial and give some points for improvement of our program, such as the categories of caregivers involved and the number and duration of contacts after parturition.

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**Keywords:** Breast-feeding; Weaning; I-change model; Attitude; Social influences; Self-efficacy

### Introduction

In the Netherlands, 80% of mothers start with breast-feeding (BF), but the rate drops rapidly during the first month postpartum to 52%, to decrease further to 35% at 3 months and 17% at 6 months [1]. To improve BF practices, initiatives have concentrated on procedures and policies in health care. Considering the low rate of long-term BF, more emphasis is needed to promote and support the continuation of BF in addition promoting its initiation. At present, Dutch programs are mainly based on increasing knowledge and not on actual support of BF. Counseling of BF is an important part of the responsibilities of the Dutch caregivers in depart-

ments of maternity and child health care. Early detection of barriers and problems of BF and monitoring of mothers at risk for early weaning are currently not embedded structurally in programs of maternity and child health care. The great popularity and the easy accessibility of the public services for maternity and child health care by the Dutch home health care organizations and their professionalism provide relevant gateways to access mothers to promote BF and preventing discontinuation.

Several programs on breast-feeding promotion and support have been developed, and reviews of randomized trials have shown that some programs were effective, while others were not [2,3]. Effective interventions generally composed a mix of elements. The goal of the study is to develop and test a program for Dutch women. Program planning was guided by the application of a planning model [4] and on analysis of behavioral determinants of breast-feeding duration [5], using the I-change model [6–8].

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The main goal of the program was to prevent mothers to refrain from discontinuation and to enhance the BF rate at 3 months by 10%, from 21% (in 1999 in the participating centers) to 31%. The rationale for the choice for 3 months is that the greatest health benefits can be reached for the baby during the first 6 months. We formulated our operational goals as follows [4]: to strengthen the support of continuation of BF (in addition to promotion of the initiation of BF) by (1) health counseling: intervening on behavioral determinants of the duration of BF by enhancing the caregiver's performance to promote and support BF using health counseling principles; (2) cooperation and continuity: to enhance cooperation, early signaling of BF problems, and continuity of care by transfer of information on individual mothers between caregivers; and (3) lactation consultancy: to take away financial and practical barriers for consulting lactation consultants [9].

Exclusive BF (EBF) was defined according the WHO definitions [10] as breast-feeding without supplemental liquids or solid foods other than medicines or vitamins; and complementary breast-feeding (CBF) was defined as breast milk complemented by formula food or solid food. Formula feeding (FF) meant feeding an infant with formula feeds with no breast-feeding at all. In this study, breast-feeding (BF) meant all feeding practices in combination with breast milk (EBF plus CBF).

## Methods

### *Study design and sample size*

We used a cluster-randomized design for the trial. The sample size was calculated for an expected absolute increase of at least 10% BF at 3 months (from 21% in the control regions, that is, the preintervention rate in the three participating Home Care Organizations, to 31% in the intervention regions). Power calculations with an alpha of 0.05 (for an one-tailed test) and a power of 80% revealed that 253 participants were needed in each group with complete follow-up.

The study received approval from the medical ethical committee of the Academic Hospital Maastricht/Maastricht University.

### *Selection and randomization of centers*

Three out of five home health care organizations in the province of Limburg, the most southern province of the Netherlands, participated. In these organizations, 10 geographically separated centers of maternity and child health care were selected. They were grouped into two clusters, A and B, based on similarity of BF rates in 1999 from the annual reports of the home health care centers (prerandomization rate) and on the number of children born in 1999 receiving care in the centers (prerandomization size), so that

clusters A and B had comparable overall prerandomization rates and sizes. On a meeting of the steering committee, who were unaware of the characteristics of the centers, a coin flip determined that the B centers would receive the experimental intervention and the A centers would receive the control intervention. The prerandomization BF rate was 19.0% in the intervention centers and 21.6% in the control centers.

### *Recruitment, informed consent, and follow-up*

Study candidates were pregnant women who applied for maternity care in the intervention or control centers of the three home health care organizations from December 2000–December 2002. About 60% of pregnant mothers were users of this maternity care; the remaining mothers used similar care from commercial organizations (not included in this study).

Typically, pregnant Dutch women apply between the 6th and 7th months of pregnancy for maternity care; then they receive a home visit by a maternity care nurse in the 7th or 8th month. The candidates from the intake list of the maternity care were sent an informed consent letter with the first questionnaire (T0) to be returned during the prepartum home visit. Those who agreed to participate received three follow-up questionnaires; the first (T1) 14 days postpartum during the postpartum home visit of the child health care nurse, and the second (T2) and third (T3) questionnaires at 2 and 5 months postpartum during the consultations at the child health center. The questionnaires had to be returned during the consultations at 1, 3, and 6 months postpartum. If participants failed to return a questionnaire, they were telephoned to obtain the most essential follow-up information including BF continuation.

The information in the informed consent letter did not reveal which center was in the control group as it was identical for the intervention and control groups. Care was taken that no other information was made public on whether a center belonged to the intervention or to the control groups to avoid selection by pregnant women towards the intervention of their choice.

Participants with infants with a birth weight less than 2,000 g were excluded from the analysis.

### *The intervention program*

To assess the behavioral determinants in our local situation, a preceding study based on the integrated model for motivational and behavioral change (I-change model) [6–8] was started in 1999. The program was targeted at pregnant women in their 7th month of the pregnancy. The operational goals were addressed by the following elements:

1. Health counseling: To facilitate the counseling process for caregivers, the health counseling (HC) model was chosen [11,12] since this model had already been applied successfully to other health promoting behaviors, such as smoking prevention [13,14]. Both process and effect

evaluations revealed its feasibility, appeal, and effectiveness [14]. The HC model was based on theories of behavioral change. The HC process consists of three phases: preparation of the advice, implementation of the advice, and maintenance. These phases were worked out in six steps addressing the behavioral determinants from our previous study [5]. We used a program matrix [15] adapted for health promotion [16,17] (Table 1).

2. Cooperation and continuity: A mother's booklet was developed to enhance cooperation between caregivers of the maternity and child health care to give early signaling of BF problems and to transfer information between caregivers. In this booklet, we described the six HC steps and mentioned the BF barriers mothers could encounter during each regular contact with caregivers. The mother's booklet was handed out, if the woman had decided to breast-feed or was still contemplating it during this visit, and the women were asked to log their BF barriers, problems, and motivation to continue BF before each next regular contact with the caregivers. The mother could also find a telephone number to reach the caregiver in case BF questions or problems arose. The caregivers in the intervention centers used the mother's booklet during each consultation and used health counseling principles with the help of the program.
3. Lactation consultancy: To enhance access to lactation consultants and to reduce financial and practical barriers for consulting them, three lactation consultants in our region were appointed and paid by Maastricht University and their services were free of charge. The lactation consultants in the intervention regions were 24 h obtainable by fax. An agreement was reached on the indications and procedures for referrals to the lactation consultants. The caregivers could fax their concerns or queries about BF on a structured form to the lactation consultant. After receiving the fax, the lactation consultants contacted the

caregiver or the mother within 24 h and tried to resolve the problems. If needed they could make home visits or follow-up calls.

For the caregivers, a counseling protocol was developed with a one-page summary for each group: for the maternity and child health care nurse and for the physician. The aim of the summary was a prompt for the steps and a resource for answering questions. The summary consisted of answers to the most frequent questions and barriers regarding early weaning that women encountered with BF.

The following caregivers were involved with the program: the maternity nurse (prepartum home visits), the nurse (postpartum home visits and consultations), and physicians (consultations) of the child health care and lactation consultants. The participation of midwives in our study could not be guaranteed since their workload had increased in recent years.

At the end of 2000, the caregivers (the maternity nurses and the child health care nurses and physicians) were trained in a 4-h session in using the program and in counseling skills by demonstration and role-play. They received a written instruction how to use the devices for early signaling of BF problems and how to solve them and received instructions for cooperation between caregivers. These instructions were discussed during the training. The training was followed by a lesson of 2 h on the role of lactation consultants and the indications for referring mothers to them. Practical problems were discussed during two refresh training sessions of 2 h.

After the training, the program was started during the prepartum home visit by the maternity nurse in the intervention centers. The program started in the beginning of 2001 and executed until the last mother had completed the 3-month follow-up. Free access to lactation consultants was

Table 1

An application of the program matrix to breast-feeding

Steps	Message	Channel	Source
Step 1 Knowledge	Supply information about BF health benefits	Prepartum home visit: - Personal communication	Maternity nurse Lactation consultant
Step 2 Motivation	Motivation to give BF? Raise motivation Give more information if necessary	- Leaflet - Mother's booklet	
Step 3 Ability	Cope with barriers Discuss/ show the way of coping		
Step 4 Intention	Probe intention towards BF		
Step 5 Practice	Give practical instructions how to give BF	Home visit during childbed: - Personal communication - Mother's booklet	Maternity assistant Child health care nurse Lactation consultant
Step 6 Continuation	Support mothers to continue BF	Home visit/ consultations: - Personal communication - Mother's booklet - Telephone calls	Child health care nurse + physician Lactation consultant

BF = breast-feeding.

restricted to the participating mothers in the intervention group. Health counseling principles and mothers' booklets were applied for all mothers in the intervention centers, including the non-participants.

#### *Baseline measurements*

In the prepartum questionnaire (T0), taken from the mothers before the first intervention, the following baseline characteristics were measured: maternal age, maternal education, previous BF experience, and the intention to give BF or formula feeding; and the ASE determinants: attitude (A), social norm (S), and self-efficacy (E). The ASE items were based on results of our previous study [5] and are fully described elsewhere [18]. Attitudes toward BF were assessed by asking the perceived advantages (pros) of BF in relation to the mother herself, to her infant, and to her partner. Beliefs regarding social norms and support were measured from significant others (such as partner, mother, sister, friends, midwife, maternity and child health care nurse and physician, colleague, and employer). A distinction was made between self-efficacy to breast-feed and to formula feed, assessing both situational and stress self-efficacy for both types of feeding.

In the first postpartum questionnaire (T1), information pertinent to the exclusion criterion was sought: the birth weight of the infant. In this questionnaire, we also asked which feeding had been started after delivery.

To assess baseline comparability of the knowledge of the caregivers about BF, we used a multiple-choice test developed by the Dutch Association for Lactation Consultants. About 3 months before the start of the intervention, this test was taken by all the caregivers of the maternity and child health care in the intervention and control regions.

#### *Outcome measurements*

As the main outcome measurement, the 3-month postpartum questionnaire (T2) asked whether the mother used exclusive BF, complementary BF, or formula at that moment and the number of weeks of exclusive or complementary BF continuation.

In the year 2000 (1 year before the start of the intervention), the caregivers in both intervention and control regions recorded registry forms during the consultations for all infants born in these regions until the last mother was included in May 2003. They recorded birth weight, feeding practices, and the timing of discontinuing of BF at birth, 1, 3, and 6 months. This registry form was pretested in one home health care organization during 1999.

#### *Process and program evaluation*

To get insight in the process of counseling, the questionnaire at 6 months postpartum (T3) in both the intervention and control groups asked whether they were satisfied with

the feeding advice of the caregivers, whether the caregivers took their opinion into account, and whether they had received any contradictory feeding advice. For the evaluation of the program, we asked mothers in the intervention group who still gave BF at 6 months postpartum (T3 questionnaire) on the usage and usefulness of the mother's booklet.

To gain insight into the process of the intervention at the caregiver level, the caregivers of the intervention and control regions filled in a questionnaire 3 months after the last mother had been included. This asked about how desirable they found to consult or to refer to a lactation consultant and their satisfaction with the care. For the program evaluation, extra questions for the caregivers in the intervention groups were added about their attitude, their support from others, and their self-efficacy to carry out the program. Furthermore, we asked whether the program took more time than usual, as well as how much time they had spent on BF counseling per consultation, the report mark of the program, their willingness to carry out the program in the future, and their opinion about the implementation on a national scale. The lactation consultants themselves recorded the BF problems they encountered and the advice they had given on a structured form at each contact with the mothers.

#### *Analyses*

Chi-square tests for categorical variables and *t* tests for continuous variables were used to compare breast- and formula-feeding mothers. For each ASE concept, a mean score was computed by averaging the scores on the items. Reliability analyses assessed the reliability (expressed as Cronbach's alpha) of the perceived pros and cons, social influences, and self-efficacy scores. The main effect of the intervention on the primary outcome [the proportion of mothers who breast-feed (EBF + CBF) at 3 months] was analyzed at two levels: at the level of the participating mothers (questionnaires) and at the level of the caregivers (registry forms) by comparing the proportion between the intervention and control groups, using the chi-square test. Univariate logistic regression was used to compute odds ratios with 95% confidence intervals. At the individual level, multivariate logistic regression was used to account for potential baseline differences of maternal age, maternal education, and previous BF experience. Modification of the intervention effect by these determinants was evaluated by testing for interaction, with a cutoff point of 0.10 for the *P* value of the interaction term.

In a multilevel analysis, a random intercepts logistic regression model was used to account for variability of BF rates between the 10 centers (including regional differences), using postcodes of the participants to group them into the regions belonging to the various centers.

Cox's regression analysis was used to test the differences between the survival rates with correction for covariates,



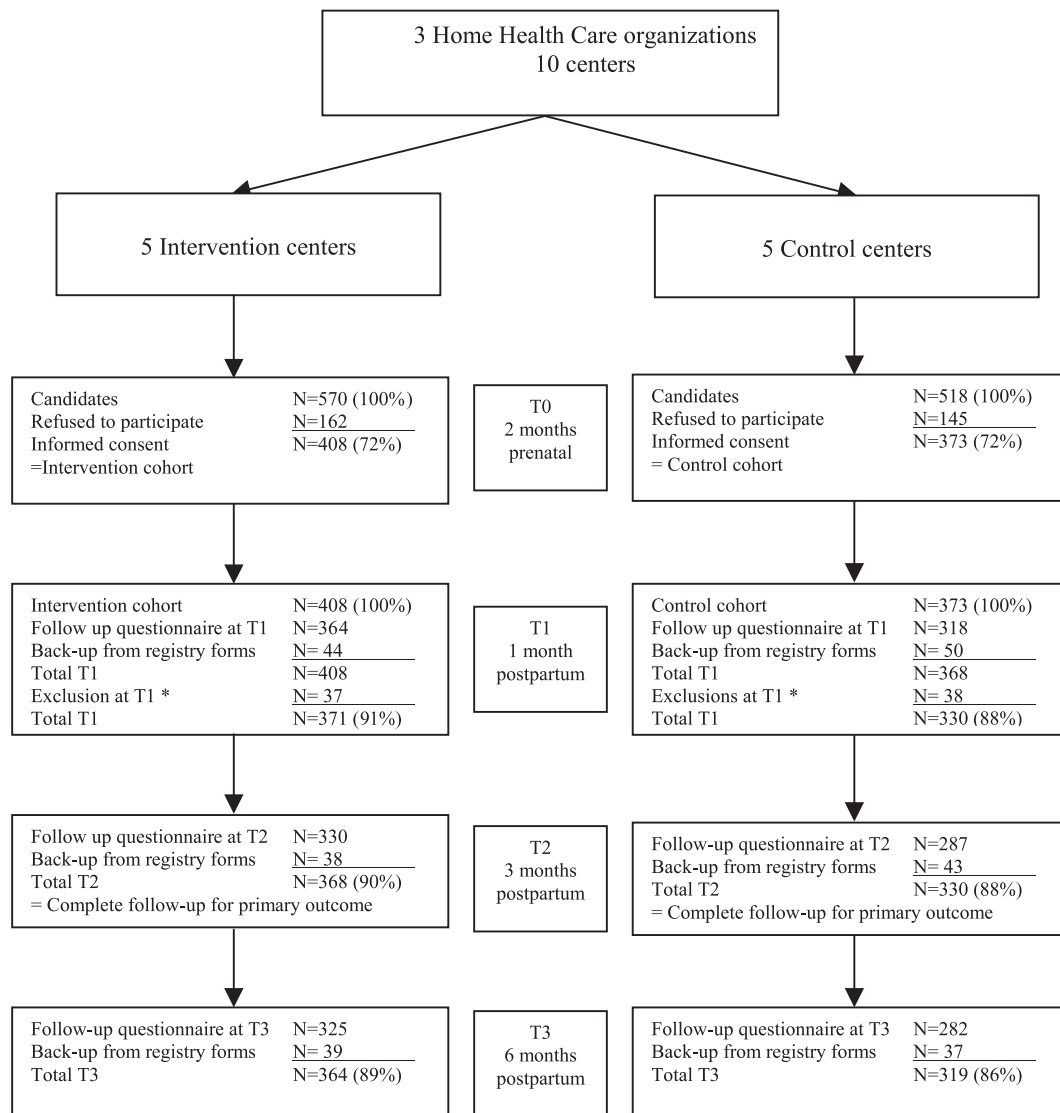
where survival was defined as continuation of BF. Survival curves corrected for covariates were derived from a stratified Cox's regression model (stratified by group).

The analyses were carried out in STATA 7.0 [19].

## Results

During the study period December 2000–December 2002, 10 centers were randomized into five intervention and five control centers. Five hundred and seventy pregnant women were applied for maternity care at the five intervention centers and 518 did so at the five control centers (Fig. 1). Of these candidates, 408 (72%) and 373 (72%) agreed to participate. At the mothers' first consul-

tation at the center at 1 month after birth, 364 mothers in the intervention group and 318 in the control group returned the first follow-up questionnaire (T1). From most nonresponders, backup data on birth weight and BF were obtained from the registry forms, so that information was complete on 408 mothers in the intervention group and 368 in the control group. Thirty-seven and 38 mothers from the respective groups were excluded so that 371 (91%) mothers remained in the intervention group and 330 (88%) in the control group (Total T1). Reasons to exclude respondents were as follows: mothers did not return the baseline questionnaire or filled in this questionnaire after the prepartum home visit when the intervention had already started ( $n = 15$ ); mothers had cancelled the maternity care of the home health care before the home



\* Exclusion: no T0 or filled in T0 to late for baseline (after prenatal home visit); no maternity care or no data available; birth weight <2,000 g or no birth weight data available

Fig. 1. The trial profile.

visit ( $n = 31$ ); the kind of maternity care was not filled in by the participant ( $n = 23$ ); and birth weight of the infants was less than 2,000 g ( $n = 15$ ) or was unknown ( $n = 21$ , the totals exceeded the totals of 37 and 38, respectively, because combinations of reasons were possible). At 3 months postpartum, the additional nonresponse to the questionnaires could almost be fully backed up with registry data so that the number of participants with complete follow-up for the primary outcome (Total T2) was 368 (90%) in the intervention group and 330 (88%) in the control group. At 6 months postpartum, the additional nonresponse was similarly backed up with the help of the registry data (Fig. 1).

The caregivers filled in 2,734 registry forms, namely, 947 forms in 2000, 1,378 in 2001, and 409 forms in 2002. These numbers are higher than the number of participating mothers because registry forms were filled in for all infants born in the intervention and control centers (including those of mothers not on the intake list for maternity care, and those of mothers who refused to participate or who were excluded). It was possible to link 406 registry forms to the

mothers' questionnaire data in an anonymous way, showing only 17 (4%) discrepancies on the duration of BF.

#### Baseline characteristics of the participants and caregivers

No dropout analyses were performed since only three participants were lost to follow-up in the intervention group and none in the control group (Fig. 1). Table 2 shows the baseline personal and ASE characteristics of the participants from the prepartum questionnaire (T0). The mean age of the pregnant mothers was 31 years ranging from 19 to 43 years; most of the mothers had a middle level of education and were primiparas. The intervention and control groups did not differ only slightly at baseline for age, maternal education, previous BF experience, and for ASE determinants. In the intervention group, fewer mothers had the intention to breast-feed (66%) than in the control group (71%).

The scores of the baseline knowledge test in caregivers were unsatisfactory ( $<5.5$  on a 1–10 scale) in 19% (6/31) at the intervention centers and 29% (6/21) at the control

Table 2

Comparison of the baseline characteristics of the complete follow-up of the intervention and control group at 3 months ( $n = 698$ )

Characteristics		Scale	Cronbach's alpha	Complete follow-up at 3 months		
				Intervention cohort	Control cohort	<i>P</i> value <sup>a</sup>
All mothers				<i>N</i> = 368 (100%)	<i>N</i> = 330 (100%)	
Intention to breast-feed				243 (66%)	233 (71%)	0.20
Maternal age	<25 years old			37 (10%)	26 (8%)	
	25–30 years old			163 (44%)	148 (45%)	
	≥31 years old			168 (46%)	156 (47%)	0.60
Maternal education <sup>b</sup>	Low			77 (21%)	61 (18%)	
	Middle			196 (53%)	194 (59%)	
	High			95 (26%)	75 (23%)	0.34
Previous BF	No, multiparas			63 (17%)	45 (14%)	
	Yes, multiparas			98 (27%)	102 (31%)	
	No, primiparas			207 (56%)	183 (55%)	0.29
ASE determinants				Mean (SD) <sup>c</sup>	Mean (SD) <sup>c</sup>	<i>P</i> value <sup>c</sup>
Attitude	Pros BF	1–5 <sup>d</sup>	0.80	3.27 (0.60)	3.24 (0.62)	0.42
	Cons BF	1–5 <sup>d</sup>	0.73	2.84 (0.45)	2.80 (0.43)	0.21
Social norm	Significant others	1–5 <sup>e</sup>	0.78	3.45 (0.59)	3.48 (0.59)	0.43
	Work	1–5 <sup>e</sup>	0.54	3.07 (0.35)	3.10 (0.44)	0.41
Social support BF	Significant others	1–5 <sup>f</sup>	0.83	2.52 (1.16)	2.60 (1.10)	0.33
	Work	1–5 <sup>f</sup>	0.79	1.39 (0.82)	1.48 (0.93)	0.15
Social support FF	Significant others	1–5 <sup>f</sup>	0.88	2.13 (0.98)	2.15 (1.08)	0.85
	Work	1–5 <sup>f</sup>	0.82	1.18 (0.88)	1.41 (0.89)	0.61
Self-efficacy BF	Situational	1–7 <sup>g</sup>	0.81	4.04 (1.15)	4.08 (1.09)	0.62
	Stress	1–7 <sup>g</sup>	0.83	3.19 (1.08)	3.17 (1.10)	0.78
Self-efficacy FF	Situational	1–7 <sup>g</sup>	0.76	5.37 (0.90)	5.37 (0.92)	0.93
	Stress	1–7 <sup>g</sup>	0.84	5.11 (1.06)	5.05 (1.07)	0.45

BF = breast-feeding; FF = formula feeding.

<sup>a</sup> From Pearson chi-square test.

<sup>b</sup> Low: primary or basic vocational school; middle: secondary vocational or high school; high: higher vocational school or university.

<sup>c</sup> From *t* test.

<sup>d</sup> 1 = fully agree, 5 = fully disagree with the advantages (pros) or disadvantages (cons) of breastfeeding.

<sup>e</sup> 1 = I must certainly breast-feed, 5 = I must certainly formula feed.

<sup>f</sup> 1 = very often support, 5 = never support for breastfeeding or formula feeding.

<sup>g</sup> 1 = very difficult, 7 = very easy to give breastfeeding or formula feeding.

centers, but the mean scores were comparable [6.0 (SD 1.00) and 5.8 (SD 1.32), respectively].

### Breast-feeding outcomes

The percentage of mothers who started breast-feeding was 68 in the intervention cohort and 72 in the control group, which was not very different from the prepartum intention in either group (66 and 71; Table 3). At 3 months, 32% continued BF in the intervention group and 38% in the control group. The multivariate logistic regression analysis (random intercepts model) did not reveal significant effect of the intervention either (OR = 0.82, 95% CI = 0.58–1.14), Table 4. Predictors of BF continuation until at least 3 months were as follows: maternal education (high level OR = 4.36; middle level OR = 1.98) compared with low level; and multiparity with previous BF experience (OR = 10.56) and primiparity (OR = 5.74) compared with multiparity without previous BF experience.

To evaluate whether the effect of the intervention depended on maternal age, maternal education, or previous BF experience, these variables were entered as interaction terms with the intervention in the multivariate logistic regression model. None of the interactions between the main outcome and the covariables reached statistical significance at the level of  $P < 0.10$ . Because the prepartum intention to give BF was a very strong determinant of BF initiation, it was not possible to adjust for intention in the same model. Consequently, a stratified analysis of Table 3 by intention was run. Of the women who intended to breast-feed, 98% (238/244) in the intervention group and 98% (228/233) in the control group initiated BF at birth (OR = 0.86, 95% CI 0.26–2.89) 48% (116/243) and 53% (122/233) continued at least 3 months (OR = 0.83,

Table 3  
Questionnaires from the mothers: breast-feeding at birth and at 3 months

	Intervention group		Control group		OR <sup>a</sup>	95% CI
	No.	%	No.	%		
Feeding at birth	371	100	330	100		
Exclusive	225	61	222	67	0.80	0.57–1.11
Complementary	29	8	16	5	1.43	0.73–2.78
Total	254	68	238	72	0.84	0.61–1.16
Feeding at 3 months	368	100	330	100		
Exclusive	99	27	104	32	0.79	0.57–1.10
Complementary	20	5	20	6	0.83	0.43–1.58
Total	119	32	124	38	0.79	0.58–1.08

Total breast-feeding = exclusive breast-feeding + complementary breast-feeding.

<sup>a</sup> From univariate logistic regression analysis.

Table 4

Determinants of breast-feeding at 3 months in multivariate logistic regression analysis

	n = 698	Conventional analysis fixed effects model		Multilevel analysis random intercepts model	
		OR	95% CI	OR	95% CI
Control	330	1.00	Reference	1.00	Reference
Intervention	368	0.82	0.62–1.07	0.82	0.58–1.14
Maternal age					
<25 years old	63	1.00	Reference	1.00	Reference
25–30 years old	311	0.99	0.56–1.75	0.99	0.53–1.85
≥31 years old	324	1.13	0.60–2.12	1.14	0.59–2.16
Maternal education <sup>a</sup>					
Low	138	1.00	Reference	1.00	Reference
Middle	390	1.98**	1.27–3.10	1.98*	1.20–3.28
High	170	4.36***	2.75–6.91	4.36***	2.50–7.59
Previous BF experience					
No, multiparas	108	1.00	Reference	1.00	Reference
Yes, multiparas	200	10.56***	5.60–19.9	10.56***	4.83–23.1
No, primiparas	390	5.74***	2.59–12.7	5.74***	2.65–12.4

<sup>a</sup> Low: primary or basic vocational school; middle: secondary vocational or high school; high: higher vocational school or university.

BF = breast-feeding.

\*\*  $P < 0.01$ .

\*\*\*  $P < 0.001$ .

Interaction terms: Intervention group  $\times$  intention,  $P = 0.57$ . Intervention group  $\times$  maternal age,  $P = 0.18$ . Intervention group  $\times$  maternal education,  $P = 0.22$ . Intervention group  $\times$  previous BF experience,  $P = 0.83$ .

95% CI 0.58–1.19). This indicates that the differences in prepartum intention between control and intervention groups did not confound the main results. The survival curves indicated only a marginal difference in the rate of continuation of BF between the intervention and control groups (Fig. 2). In the Cox's regression analysis, the

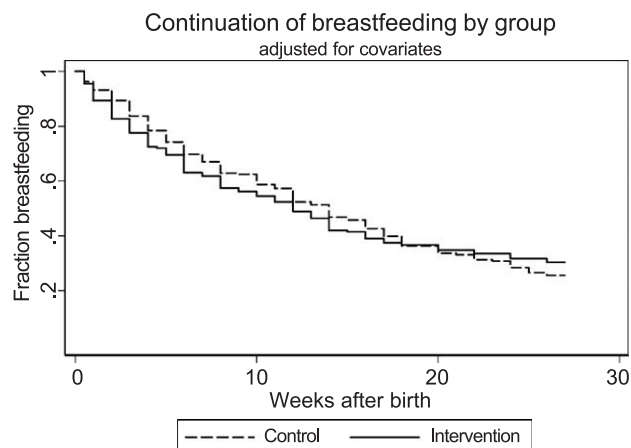


Fig. 2. The survival curve of the continuation of breast-feeding adjusted for covariates (maternal age, maternal education, and previous breast-feeding experience; intervention group  $n = 245$ , control group  $n = 224$ , from Cox's regression analysis).



hazard ratio for discontinuation of BF was 0.99 (95% CI 0.93–1.06) when comparing intervention and control groups (controlling for maternal age, maternal education, and previous BF experience).

At the level of the caregivers, in the year before the intervention (2000), the rate of BF reported in the registry forms in the intervention centers was 25.8% (123/477) but 31.1% (146/470) in the control centers. In the first year of the intervention period (2001), the rate was 31.0% (207/668) in the intervention centers and 27.6% (196/710) in the control centers. In the last half year of the intervention period (2002), the rates were 30.0% (76/253) and 30.1% (47/156), respectively. When the rates of 2001 and 2002 were taken together, none of the differences was statistically significant (difference in trend between 2000 and 2001 + 2002,  $P = 0.32$ ; difference between intervention and control group,  $P = 0.97$ ; interaction between trend and group,  $P = 0.09$ ; from multilevel logistic regression analysis with random intercepts for the child health centers). In sum, no intervention effect was found.

### Process evaluation

Opinions of mothers about the feeding advices given by the caregivers were not more positive in the intervention

group than in the control group, with the exception that they reported slightly less contradictory feeding advice ( $P = 0.04$ ) (Table 5).

Eighty percent of the caregivers reported that they obtained good or sufficient behavioral skills to carry out the program. Of the 25 caregivers in the intervention centers, 96% paid attention to the pros of BF, 52% to the cons, 72% to the barriers, and 68% to the social influences of BF during the contacts with the mothers. Eighty-eight percent always (or mostly) experienced support from their colleagues, 80% from the lactation consultants, and 72% from the management. However, only 33% almost (or mostly) experienced support from the midwives. All the caregivers 100% reported that they knew the materials and generally used them. Only 2 out of 25 caregivers from the intervention centers reported that they had been substituted by caregivers from the control centers (for 10% and 25% of their time, respectively) and 3 out of 25 caregivers had substituted for a caregiver in the control centers (for 5%, 5% and 10% of their time).

Caregivers in the intervention centers were slightly more positive about the lactation consultants than those in the control centers, but the differences did not reach statistical significance (Table 5).

Table 5

Opinions of mothers about the feeding advices and opinions of caregivers about the care of the lactation consultants

	Scale <sup>a</sup>	No.	Intervention cohort, mean (SD) <sup>b</sup>	No	Control cohort, mean (SD) <sup>b</sup>	<i>P</i> value <sup>b</sup>
<i>Opinions of mothers (n = 617) about feeding advice</i>						
Are you satisfied with feeding advice by						
Hospital nurse (n = 342)	1–5	187	2.53 (1.09)	155	2.35 (1.07)	0.13
General practitioner (n = 242)	1–5	139	2.31 (0.84)	105	2.31 (0.89)	0.96
Pediatrician (n = 226)	1–5	127	2.35 (0.95)	99	2.30 (0.89)	0.73
Child health care nurse (n = 568)	1–5	300	1.98 (0.75)	268	2.05 (0.76)	0.30
Child health care physician (n = 566)	1–5	297	2.01 (0.79)	269	2.10 (0.78)	0.16
Lactation consultant (n = 101)	1–5	73	2.07 (0.84)	28	2.18 (1.02)	0.58
Did the caregivers reckon with your own opinion?						
Hospital nurse (n = 484)	1–5	262	3.29 (1.02)	222	3.30 (1.04)	0.87
General practitioner (n = 487)	1–5	260	3.41 (0.85)	227	3.39 (1.00)	0.78
Pediatrician (n = 462)	1–5	244	3.29 (0.88)	218	3.33 (0.93)	0.60
Child health care nurse (n = 591)	1–5	312	3.76 (0.92)	279	3.71 (1.05)	0.60
Child health care physician (n = 597)	1–5	317	3.76 (0.91)	280	3.67 (1.04)	0.27
Lactation consultant (n = 395)	1–5	211	3.40 (0.92)	184	3.27 (0.97)	0.15
Satisfaction with the reach of caregivers? (n = 610)	1–5	327	2.05 (0.87)	283	2.03 (0.84)	0.84
Did you receive contradictory feeding advice? (n = 616)	1–5	329	1.71 (0.45)	287	1.79 (0.41)	0.04
<i>Opinions of caregivers (n = 40) about the care of lactation consultants</i>						
How desirable is it for you to have the possibility						
To refer to them?	1–5	25	3.92 (0.28)	15	3.73 (0.88)	0.34
To consult them?	1–5	25	3.96 (0.20)	15	3.86 (0.35)	0.27
Satisfaction with						
Their reach	1–5	25	2.60 (0.76)	15	2.40 (0.91)	0.48
Their quality of care	1–5	25	2.96 (0.79)	15	2.80 (0.68)	0.50
Their quickness of response to caregivers	1–5	25	2.64 (0.76)	15	2.60 (0.74)	0.87
Their quickness of response to mothers	1–5	25	2.80 (0.76)	15	2.67 (0.62)	0.55
Their report to caregivers	1–5	25	2.76 (0.97)	15	2.27 (0.70)	0.07

<sup>a</sup> 1 = not at all, 5 = very much.

<sup>b</sup> From *t* test.

### Program evaluation

The introduction training was followed by 19 of the 25 caregivers. The other six persons were absent during this training or started to work after the training and received a group introduction. Twenty-two caregivers followed the refresh trainings.

Ninety-six percent of the mothers in the intervention group received the mother's booklet, which was used in most contacts by 57%, by 58% of the child health care nurses, and by 53% of the child health care physicians.

With regard to the program, 56% of the caregivers found it (fairly) difficult to carry out but 64% succeeded in carrying it out always (or mostly) at each contact. Ninety-six percent found the program clear and understandable, and 92% were stimulated by the program to give attention to BF always (or mostly). When we asked whether this program would merit implementation on a national scale, 84% reported that this would be (very) meaningful and 54% were willing to carry it out in the future. Forty-four percent reported that the program took more time than usual: 80% reported that they had longer home visits (12 min more per caregiver), 27% had more home visits (4 min more per month per caregiver), 72% had longer consultations (7 min more per caregiver), and 44% had more consultations (12 consultations more per month per caregiver). During the first 3 months, the mean time they spent on BF counseling during the home visits was 16.6 min (SD 9.4,  $n = 16$ ) in the intervention group and 16.9 min (SD 6.1,  $n = 14$ ) in the control group; the mean time spent during the consultations at the child health care centers was 9.1 min (SD 7.4,  $n = 19$ ) in the intervention group and 5.8 min (SD 1.5,  $n = 18$ ) in the control group. The caregivers gave the program a report mark of 7.3 (SD 0.74) on a scale of 1–10 (1 = *very low* to 10 = *excellent*). Sixty-four mothers (16%) from the intervention group were referred to the lactation consultants, namely, 19 (30%) by caregivers of the maternity care, 44 (69%) by caregivers of the child health care, while one mother (2%) contacted the lactation consultant directly. Most common reasons for referral were doubt about drinking of the infant (21%), crying infant (11%), and pain during feeding (11%).

### Discussion

There were no significant differences between the intervention and control groups in the rates of BF at birth, or 3 months, or later. Before discussing the implications, we will review the methodological quality of the trial: the comparability of the centers, caregivers, and participants; the contrast between the intervention and control groups and the comparability of cointerventions; the comparability of the outcome measurement; and the statistical power.

With respect to the comparability of the centers, self-selection of the centers was excluded because all the home

health care organizations agreed to participate before the start of the trial and all 10 centers continued without dropout. To avoid self-selection of pregnant women to the intervention of their choice, no information was made public whether a center participated in the intervention or control groups; and nonparticipation in the trial occurred before the information was given about the intervention. We had no selective dropout by migration of mothers to another center if they were not pleased with the intervention. At baseline, there was no difference in knowledge between the caregivers. Two years before the start of the intervention (1999), the 3-month BF rates did not differ between the intervention and control regions due to the prestratification and cluster randomization; however, in the year before the intervention (2000), the rate was lower in the intervention centers (25.8%) than in the control centers (31.1%). We were surprised by this difference but noted that BF rates varied greatly between the centers as well as over the years. The variability between the centers was taken into account in the multilevel analysis. Participating mothers in the intervention and control groups were reasonably comparable with regard to prognostic variables at baseline, but a difference in the intention to breast-feed was present to the detriment of the intervention group (66% vs. 71% in the control group). However, in a stratified analysis, no intervention effect was found in the subgroups of women with and without prepartum intention to carry out BF.

With respect to the contrast between intervention and control groups, the execution of the intervention was according to the planning: all the caregivers followed the training and received two refresh trainings; during the intervention period, there were few new caregivers who also received a short individual training. Caregivers reported that they gave attention to the attitudes, social support, and self-efficacy problems during most of the consultations, had self-confidence in carrying out the program, and felt support from others. The majority of mothers and caregivers used the materials. To avoid an intervention effect resulting from the informed consent procedure and the questionnaires, the informed consent letter was identical for the intervention and the control groups, blinding the aim of increasing BF rates; and the questionnaires had similarly phrased questions about the ASE determinants for formula feeding and BF. The centers were geographically separated. Hence, exchange of information between caregivers of intervention and control centers was avoided. Nevertheless, we cannot exclude that the caregivers had exchanged their knowledge of the training in the health counseling and stimulated each other to promote BF. However, the specific effect of such an exchange could have only been minimal because health counseling is a specific approach, which only can be learned by training. The instruction materials and other supporting measures (the mother's booklet and free access to lactation consultants) were only available in the intervention group. With respect to cointerventions, no new activities that could have diminished the contrast between the intervention and

control groups were introduced during the intervention period.

With respect to the comparability of outcome measurement, the participants and the caregivers could not be blinded for the intervention; consequently, the outcome measurement could have been influenced by social desirability or by expectations about the intervention effect. However, if this were the case, this would have led to discrepancies between the BF data from the questionnaires and from the registry forms of the individual mothers. A comparison found only 4% discrepancies. The follow-up was nearly complete; differential loss to follow-up between the intervention and control groups can therefore be excluded.

The intended size of our trial ( $253 + 253$ ) was determined to detect an absolute difference of 10% between the BF rates at 3 months in the intervention group (31%) and the control group (21%) with 80% power ( $\alpha$  0.05, one sided). The actual number of participants ( $368 + 330$ ) far outnumbered this, and the actual BF rate in the control group was higher (38%) to the effect that a 10% higher rate in the intervention group (48%) could have been detected with a power of 83%. In the multilevel analysis, some power is lost due to the variation between clusters. The upper confidence limit of the odds ratio of the main intervention effect (1.14) indicates that it is unlikely that a large intervention effect was missed.

## Conclusion

We have no indications of major biases in the design or execution of the trial. Studies in other fields have shown that the effectiveness of health promotion programs is greatly dependent on the quality of planning [20]. In our study, we addressed the steps identified by most planning models [4] and developed our health counseling model on the determinants resulting from the study [5]. Furthermore, we reviewed intervention trials for BF promotion programs. Effective programs were programs containing a mix of interventions. In spite of fulfilling these conditions, the present program was not shown to be effective.

Several explanations for the lack of effectiveness can be given. First, the choice of professionals included in the intervention was limited. We could not employ midwives, maternity assistants, or pediatricians in our research study since their practices overlapped the child health care centers to such an extent that it would not be possible to create separate intervention and control centers and had therefore a gap in support in the perinatal period. Mothers received only an intervention during the home visits 2 months before and 14 days after the parturition and the following intervention took place at 1 month. We could not use mass media or regional magazines to support the program since contamination had to be avoided.

A second explanation is that health counseling in this setting has certain limitations. The health counseling model has been successfully applied to smoking prevention; nev-

ertheless, there is a difference between BF and smoking. Discontinuation of BF is mostly irreversible, contrary to smoking relapse for which repeated opportunities are possible. In addition, there is a cheap and easy alternative available for BF (formula feeding) and especially easy for working mothers. Possibly health counseling lays too much emphasis on the difficulties of BF, while women like to see BF as easy and cozy. Such an adverse effect may also have been evoked by attention to early detecting of BF problems.

A third explanation is that the necessary conditions were possibly not present to let the program be successful. A precondition of the program was that the knowledge of caregivers about breast-feeding was sufficient in the region. We assumed that knowledge would be sufficient because the home health care organizations organized annual breast-feeding introduction and booster trainings, before and during the study period (and not different between intervention and control groups). Furthermore, baseline results as measured in the trial revealed that most caregivers scored sufficiently on a breast-feeding knowledge test. A limitation of this test may be, however, the lack of reference data for this test in the Netherlands. Hence, we cannot be completely confident that the condition of sufficient knowledge of breast-feeding was met.

A fourth explanation for the absence of effectiveness might be a diffuse increase of BF attention in both regions, at the level of the participants by a possible intervention effect of the repeated questionnaires and, at the level of the caregivers by increased attention for BF in their organizations. On the other hand, much attention was devoted to early detection of BF problems. We compared the percentages from our study with the annual national percentages [21]. During the last 5 years (1997–2002), there was a rise in percentages of exclusive BF at birth from 70% to 80% (and at 3 months from 17% to 35%). Possibly, the increased attention by professionals and mass media may have contributed to this increase. In the Netherlands, the certification of the maternity care in relation to the Baby Friendly Hospital Initiative had a positive effect on the initiation but not on the duration of BF [21]. Planned programs such as our program or the Baby Friendly Hospital Initiative appear not to contribute to this increasing trend in BF duration.

Lastly, availability of free lactation consultancy was not shown to make a difference in BF continuation in spite of its high uptake in the intervention group. We have found no trials in which lactation consultancy was evaluated as an isolated intervention, but one trial that included it in combination with early discharge showed that it was effective [22].

## Recommendations

To summarize, we found no effect of our BF promotion and support program, and no major flaws in the design or execution of the trial could explain this. We conclude that

none of the elements in our program is effective (health counseling; early signaling and referral for free lactation consultancy). Programs of BF promotion reviewed by Fairbank et al. [2] or BF support reviewed by Sikorski et al. [3] were shown to be effective in many trials but ineffective in many others, and when comparing them it is hard to tell which mix or intensity of interventions is decisive. Points of improvement in our program are the categories of caregivers involved (maternity assistants, midwives, peer counselors), the number and duration of contacts, especially in the first weeks after parturition, and more emphasis on the continuation steps in health counseling with avoidance of over-emphasis on BF problems. Further improvements of breastfeeding support may need a combination of attention to behavioral determinants at the caregivers' level (mesolevel) and environmental and cultural change (macrolevel), such as the conditions for combining work and breast-feeding. The latter may have great impact, as can be seen by the high BF rates in Scandinavian countries, but goes beyond the kind of programs that can be experimentally tested.

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